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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,770	07/01/2003	James E. Brewer	A03P1047	4998

36802 7590 08/30/2007

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
GEDEON, BRIAN T	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
08/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,770	BREWER ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment filed 22 June 2007.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declaration do not have the correct statement with respect to the duty to disclose.

CORRECT STATEMENTS should read:

- "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

INCORRECT STATEMENTS:

- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56"

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 6, 7, 15-19, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Manrodt et al. (US Patent no. 6,445,952).

In regard to claims 1, 2, 4, 6, 7, 15-19 and 22, Manrodt et al. describe an apparatus and method for detecting dislodgement at a heart tissue/pacing lead electrode interface; the dislodgement detection approach can be used in any of the four chambers of the heart, col 2 lines 15-21. The apparatus and method can be embodied as a dual chamber implantable pulse generator (IPG) that is programmable, col 4 lines 46-56. In accordance with figure 4, an IPG 403 is depicted with and atrial lead 401 and a ventricular lead 421. The atrial lead 401, with electrodes 406 and 408, can operate in either bipolar pacing mode or unipolar pacing mode, wherein the IPG housing is utilized as a reference electrode during unipolar mode. The ventricular lead 421, with electrodes 426 and 428, can operate in either bipolar pacing mode or unipolar pacing mode, wherein the IPG housing is utilized as a reference electrode during unipolar mode. One of the electrodes on both the atrial 401 and ventricular 421 leads are ring electrodes, col 9 lines 12-15. The dislodgement testing procedures is conducted by

delivering an electrical signal (e.g., a pace signal) to the atrium (i.e., first chamber) using an atrial lead and corresponding electrodes (i.e., a first electrode). After a relatively short time delay, the delivered electrical signal is sensed in the ventricle (i.e., a second chamber) using a ventricular lead and its corresponding electrodes (i.e., a second electrode), col 10 lines 54-65. A pacing threshold parameter measurement is taken using the electrodes of the ventricular leads, col 10 lines 61-65. The pacing threshold parameter is preferably a voltage value, see abstract.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 5, 20, and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Manrodt et al. (US Patent no. 6,445,952).

In regard to claims 3, 5, 20, and 21, Manrodt et al. substantially describes the invention as claimed, except does not claim that the first or second chambers may be one of a right ventricle, left ventricle, or in a vessel. Manrodt et al. can be used in any of the four chambers of the heart, col 2 lines 18-21. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus and method of Manrodt et al. by placing leads in other locations of the heart

since Manrodt et al. suggest that any chamber can be used, and further it is well known in the art to be able to place leads in any of the cardiac chambers or vessels.

7. Claims 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manrodt et al. (US Patent no. 6,445,952) in view of Digby (US Patent no. 4,173,230).

In regard to claims 8 and 9, Manrodt et al. substantially describe the invention as claimed except do not teach sensing or pacing during the refractory period. Digby teaches that sensing and pacing can occur during a refractory period, col 4 lines 1-10. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to sense and pace during the refractory period in order to artificially extend it.

8. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manrodt et al. (US Patent no. 6,445,952) in view of Burnes et al. (US Publication no. 2003/0204212).

In regard to claims 10-12, Manrodt et al. substantially describe the invention as claimed except for measuring parameters relating to the dimensions of the heart. As set forth in Burnes et al. impedance is measured between two sensing locations, which in view of a multi-chamber pacing system implies that impedance can be measured between two different chambers of the heart. The impedance measurements are associated with cardiac geometry since Burnes et al. teach that maximum impedance is indicative of minimum cardiac volume, para 0018. Further, impedance measurements are taken across the heart at certain cardiac cycle times as a measure of chamber expansion or contraction, which the Examiner interprets as being parameters related to

cardiac geometry, para 0012. In view of the fact that impedance is the ratio between voltage potential and current and of the teachings regarding impedance sensing of Burnes et al., the Examiner takes the position that potential is necessary if not inherently being measured. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Manrodt et al. with the methods for dimension measurements of Burnes et al. since both references teach methods for sensing potentials across the heart in order to ascertain parameters relating to dimensions (i.e., Manrodt et al. determine as distance between electrodes, and Burnes et al. determine cardiac geometry.

In regard to claim 13, the contraction and volume parameters detected by Burnes et al. are indicative of congestive heart failure, para 0002-0003.

In regard to claim 14, Burnes et al. apply a cardiac resynchronization therapy, para 0012.

Response to Arguments

9. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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